

PATENT  
 Docket No. P-10909.00  
 (M&R 134.01910101)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 03 2004

Applicant(s): Benz et al. ) Group Art Unit: 1713  
 )  
 Serial No.: 10/663,926 ) Examiner: Unassigned  
 Confirmation No.: 2299 )  
 )  
 Filed: September 16, 2003 )  
 )  
 For: COMPOUNDS CONTAINING QUATERNARY CARBONS AND SILICON-  
 CONTAINING GROUPS, MEDICAL DEVICES, AND METHODS

OFFICIAL

FACSIMILE TRANSMISSION TO THE PTO

Commissioner for Patents  
 Mail Stop Amendment  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

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Mueting, Raasch & Gebhardt, P.A.  
 Customer Number: 26813

June 3, 2004  
 Date

By: Nancy A. Johnson  
 Nancy A. Johnson  
 Reg. No. 47,266  
 Direct Dial (612)305-4723

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June 3, 2004  
 Date

Signature: Sam Her  
 Name: Sam Her

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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For: COMPOUNDS CONTAINING QUATERNARY CARBONS AND SILICON- CONTAINING GROUPS, MEDICAL DEVICES, AND METHODS			

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the continuing duty of candor and good faith that is to be demonstrated before the United States Patent and Trademark Office (USPTO), enclosed for the Examiner's information is a copy of the written opinion from a foreign counterpart (PCT/US03/29153). Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability.

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

**Information Disclosure Statement**

Page 2 of 2

Applicant(s): Benz et al.

Serial No.: 10/663,926

Confirmation No.: 2299

Filed: September 16, 2003

For: COMPOUNDS CONTAINING QUATERNARY CARBONS AND SILICON-CONTAINING GROUPS,  
MEDICAL DEVICES, AND METHODS

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3<sup>rd</sup> day of JUNE, 2004, at 9:30 AM (Central Time).

Sam Her  
Name: Sam Her

June 3, 2004  
Date

Respectfully submitted for

Benz et al.  
By  
Mueting, Raasch & Gebhardt, P.A.  
P.O. Box 581415  
Minneapolis, MN 55458-1415  
Telephone (612)305-1220  
Facsimile (612)305-1228  
Customer Number 26813

By: Nancy A. Johnson  
Nancy A. Johnson  
Reg. No. 47,266  
Direct Dial (612)305-4723

## PATENT COOPERATION TREATY

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MAY 17 2004

MUETING &amp; RAASCH

PCT

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:	
MUETING, Ann, M. Mueting, Raasch & Gebhardt, P.A. P.O. Box 581416 Minneapolis, MN 55458-1416 ETATS-UNIS D'AMERIQUE	

## WRITTEN OPINION

(PCT Rule 66)

7/11/04 REMINDER  
8/11/04 Resp DueDate of mailing  
(day/month/year) 11.05.2004Applicant's or agent's file reference  
P-10909.01 134.01910201

REPLY DUE

within 3 month(s)  
from the above date of mailingInternational application No.  
PCT/US 03/29153International filing date (day/month/year)  
16.09.2003Priority date (day/month/year)  
17.09.2002International Patent Classification (IPC) or both national classification and IPC  
C08G18/61Applicant  
MEDTRONIC, INC.

- This written opinion is the first drawn up by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - I  Basis of the opinion
  - II  Priority
  - III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV  Lack of unity of invention
  - V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI  Certain documents cited
  - VII  Certain defects in the international application
  - VIII  Certain observations on the International application
- The applicant is hereby invited to reply to this opinion.
 

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the International preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 17.01.2005

Name and mailing address of the international  
preliminary examining authority:European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 TX: 523656 epmu d

Authorized Officer

olde Scherer, B

Formalities officer (incl. extension of time limits)  
Aperribay, I

**WRITTEN OPINION**

International application No. PCT/US 03/29153

**I. Basis of the opinion**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

**Description, Pages**

1-33 as originally filed

**Claims, Numbers**

1-77 as originally filed

**Drawings, Sheets**

1/1 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5.  This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

## WRITTEN OPINION

International application No. PCT/US 03/29153

#### **IV. Lack of unity of invention**

1. In response to the invitation (Form PCT/IPEA405) to restrict or pay additional fees, the applicant has:
  - restricted the claims.
  - paid additional fees.
  - paid additional fees under protest.
  - neither restricted nor paid additional fees.
2.  This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

see separate sheet
3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:
  - all parts.
  - the parts relating to claims Nos. .

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

<b>1. Statement</b>			
<b>Novelty (N)</b>		<b>Claims</b>	<b>1-77</b>
<b>Inventive step (IS)</b>		<b>Claims</b>	
<b>Industrial applicability (IA)</b>		<b>Claims</b>	

## 2. Citations and explanations

see separate sheet

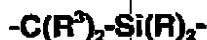
**WRITTEN OPINION  
SEPARATE SHEET**

International application No. PCT/US03/29153

**Re Item IV****Lack of unity of invention**

1. The common concept linking together the independent claims 1, 17, 40, 50, 57, 71, 76 and 77 is the following:

the presence of the structural unit



which is the most reduced form of the Markush-type structural formulation ( $n = m = r = 0$ ;  $p = s = q = 1$ ; and  $Z = -\text{C}(\text{R}^3)_2-$ )

This common concept is not novel, see Item V, paragraph 4 below.

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: US-B1-6 420 452 (GUNATILLAKE ET AL) 16 July 2002 (2002-07-16)
- D2: EP-A-0 661 332 (KANEGAFUCHI CHEMICAL INDUSTRY) 5 July 1995 (1995-07-05)
- D3: WO 98/50086 A (MEDTRONIC) 12 November 1998 (1998-11-12)
- D4: EP-A-0 940 405 (WACKER-CHEMIE) 8 September 1999 (1999-09-08)

1. The present application relates to:
  - (i) a medical device comprising a polymer comprising a group of a certain formula (claims 1-16),
  - (ii) a medical device comprising a polymer prepared from a compound of a certain formula (claims 17-39),
  - (iii) a polymer comprising a group of a certain formula (claims 40-49),
  - (iv) a polymer comprising an urea and/or an urethane group and a group of a

**WRITTEN OPINION  
SEPARATE SHEET**

International application No. PCT/US03/29153

certain formula (claims 50-56),  
(v) a polymer prepared from a compound of a certain formula (claims 57-70),  
(vi) a compound of a certain formula (claims 71-75)  
(vii) a method of making a polymer comprising a group of a certain formula (claim 76), and  
(viii) a method of making a compound of a certain formula (claim 77).

2. The seven (7) identified independent claims are linked together due to the presence of the structural unit in its most reduced Markush-type form ( $n = m = r = 0$ ;  $p = s = q = 1$ ; and  $Z = -C(R^3)_2-$ ):

$-C(R^3)_2-Si(R)_2-$

3. It should be noted that due to the feature "comprising" the claims on file are by no means restricted to the mandatory features expressed in said claims. Additional components or process steps may present to an unlimited extent.

4. Document D1 discloses silicon containing chain extenders which are useful in the preparation of (polyurethane-containing) polymers, which polymers are useful in the preparation of medical devices (see column 1, lines 10-16 and claims 1-48).

Said chain extender is exemplified by the Markush-type formula (I)



It is immediately evident that said formula (I) contains (= comprises!) the structural unit  $-C(R^3)_2-Si(R)_2-$ . The ligands  $R^3$  and  $R$  are the same as presently claimed. Therefore, said disclosed formula (I) virtually overlaps the Markush-type formula presently claimed.

Thus, the subject matter of the claims on file lacks novelty (Art. 33(2) PCT).

5. Document D2 discloses (see page 3, lines 6-27) structures which comprise the structural unit  $-C(R^3)_2-Si(R)_2-$ . The ligands  $R^3$  and  $R$  are the same as presently claimed.

**WRITTEN OPINION  
SEPARATE SHEET**

International application No. PCT/US03/29153

Thus, the subject matter of the claims on file, more specifically at least independent claim 40 lacks novelty (Art. 33(2) PCT).

6. Document D3 discloses medical devices comprising segmented polymers comprising urethane groups as well as silicon groups (see page 6, line 3 to page 8, line 24; page 15, line 11 to page 16, line 18; claims 1, 9-13; examples 7-13, 17-20). In the examples polydimethylsiloxane diol (PDMS diol) is used to build in the soft segmented groups. As far as is known to the authorised officer exhibits PDMS diol the general structure  $\text{HO}-(\text{Si}(\text{CH}_3)_2-\text{O})_n$ , which structure does not comprise the structural unit  $-\text{C}(\text{R}^3)_2-\text{Si}(\text{R})_2-$  as mandatory required by the present application.

Thus, D3 does not prejudice novelty of the present application.

7. Document D4 discloses organosilicone compounds which do not prejudice novelty of the claims on file for the following reasons:

If one selects the indices  $a=1$  and  $b=2$  then formula (I) reduces to  $(\text{R}^3\text{HC}=\text{CH}-)_2\text{Y}-(\text{R}^2)_a-\text{Si}(\text{R})_2-\text{O}-$ . Since neither  $\text{R}^2$  nor  $\text{Y}$  are structurally identified, no conclusion can be drawn whether  $-\text{Y}-\text{Si}(\text{R})_2-$  (if  $a=0$ ) or  $-(\text{R}^2)-\text{Si}(\text{R})_2-$  (if  $a=1$ ) meets the structural unit  $-\text{C}(\text{R}^3)_2-\text{Si}(\text{R})_2-$  as mandatory required by the present application.

8. The applicant is invited to file a new set of claims of which he feels meets the requirements of the PCT.
9. The applicant is given the opportunity to comment upon the literature cited in the International Search Report in view of any new claim to be filed (Rule 51 (1) (a) (i) PCT and PCT Guidelines C-II 4.3).
10. The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments un-

**WRITTEN OPINION**  
**SEPARATE SHEET**

International application No. PCT/US03/29153

der the PCT procedure, however minor these may be.

11. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

12. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply rather than be incorporated into the application, Article 34(2)(b) PCT.